

APPENDIX A

Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories

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PREFACE

Throughout its deliberation concerning these quality standards, the DNA Advisory Board recognized the need for a mechanism to ensure compliance with the standards. An underlying premise for these discussions was that accreditation would be required to demonstrate compliance with the standards and therefore assure quality control and a quality program. Accordingly, the Board recommends that forensic laboratories performing DNA analysis seek such accreditation with all deliberate speed. Additionally, the Board strongly encourages the accrediting bodies to begin positioning themselves to accommodate the increasing demand for accreditation.

INTRODUCTION

Forensic DNA identification analysis currently involves forensic casework and convicted offender analyses. These complementary functions demand adherence to the highest analytical standards possible to protect both public safety and individual rights. Separate standards have been drafted for laboratories performing these functions. This separation is an acknowledgment of the differences in the nature or type of sample, the typical sample quantity and potential for reanalysis, and specialization that may exist in a laboratory. Standards for convicted offender laboratories, in some instances, are less stringent than for those performing forensic casework analyses, but in no case should the two documents be interpreted as conflicting.

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

MECHANISM TO RECOMMEND CHANGES TO STANDARDS

Once the Director of the Federal Bureau of Investigation (FBI) has issued standards for quality assurance for convicted offender DNA testing, the DNA Advisory Board may recommend revisions to such standards to the FBI Director, as necessary. In the event that the duration of the DNA Advisory Board is extended beyond March 10, 2000, by the FBI Director, the Board may continue to recommend revisions to such standards to the FBI Director. In the event that the DNA Advisory Board is not extended by the FBI Director after March 10, 2000, the Technical Working Group on DNA Analysis Methods (TWGDAM) may recommend revisions to such standards to the FBI Director, as necessary.

EFFECTIVE DATE

These Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories take effect April 1, 1999.

REFERENCES:

American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB), *ASCLD-LAB Accreditation Manual*, January 1994, and January, 1997.

Federal Bureau of Investigation, *Quality Assurance Standards for Forensic DNA Testing Laboratories*, (1998)

International Standards Organization (ISO)/International Electrotechnical Commission (IEC), *ISO/IEC Guide 25-1990*, (1990) American National Standards Institute, New York, NY.

Technical Working Group on DNA Analysis Methods, "Guidelines for a Quality Assurance Program for DNA Analysis," *Crime Laboratory Digest*, April 1995, Volume 22, Number 2, pp. 21-43.

42 Code of Federal Regulations, Chapter IV (10-1-95 Edition), Health Care Financing Administration, Health and Human Services.

1. SCOPE

The standards describe the quality assurance requirements that a government laboratory which is defined as a facility in which convicted offender DNA testing is regularly performed should follow to ensure the quality and integrity of the data and competency of the laboratory. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

- (a) Administrative review is an evaluation of the documentation for consistency with laboratory policies and for editorial correctness.
- (b) Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.
- (c) Analytical procedure is an orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.
- (d) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.
- (e) Batch is a group of samples analyzed at the same time.
- (f) Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system

or values represented by a material and the corresponding known values of a measurement.

- (g) CODIS is the Combined DNA Index System administered by the FBI. It houses DNA profiles from convicted offenders, forensic specimens, population samples and other specimen types.
- (h) Commercial test kit is a preassembled kit that allows the user to conduct a specific DNA identification test.
- (i) Convicted offender is an individual who is required by statute to submit a standard sample for DNA databasing.
- (j) Convicted offender database (CODIS) manager or custodian (or equivalent role, position, or title as designated by the laboratory director) is the person responsible for administration and security of the laboratory's CODIS.
- (k) Convicted offender standard sample is biological material collected from an individual for DNA analysis and inclusion into CODIS. See also database sample.
- (l) Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter.
- (m) Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use in order to prevent unnecessary loss of sample.
- (n) Database sample is a known blood or standard sample obtained from an individual whose DNA profile will be included in a computerized database and searched against other DNA profiles.
- (o) Examiner/analyst (or equivalent role, position, or title as designated by the laboratory director) is an individual who conducts and/or directs the analysis of samples, interprets data and reaches conclusions.
- (p) Known samples are biological material whose identity or type is established.
- (q) Laboratory is a government facility in which convicted offender DNA testing is performed or a government facility who contracts with a second entity for such testing.
- (r) Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are individual(s) who perform laboratory duties and do not analyze samples.
- (s) NIST is the National Institute of Standards and Technology.

- (t) Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of (1) denaturation of the template; (2) annealing of primers to complementary sequences at an empirically determined temperature; and (3) extension of the bound primers by a DNA polymerase.
- (u) Proficiency test sample is biological material whose DNA type has been previously characterized and which is used to monitor the quality performance of a laboratory or an individual.
- (v) Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:
 - (1) Internal proficiency test is one prepared and administered by the laboratory.
 - (2) External proficiency test, which may be open or blind, is one which is obtained from a second agency.
- (w) A Qualifying test measures proficiency in both technical skills and knowledge.
- (x) Quality assurance includes the systematic actions necessary to demonstrate that a product or service meets specified requirements for quality.
- (y) A quality manual is a document stating the quality policy, quality system and quality practices of an organization.
- (z) Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.
- (aa) Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.
- (bb) Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.
- (cc) Restriction Fragment Length Polymorphism (RFLP) is generated by cleavage by a specific restriction enzyme and the variation is due to restriction site polymorphism and/or the number of different repeats contained within the fragments.
- (dd) Review is an evaluation of documentation to check for consistency, accuracy, and completeness.
- (ee) Second agency is an entity or organization external to and independent of the laboratory and which performs DNA identification analysis.

- (ff) Secure area is a locked space (for example, cabinet, vault or room) with access restricted to authorized personnel.
- (gg) Subcontractor is an individual or entity having a transactional relationship with a laboratory.
- (hh) Technical manager or leader (or equivalent position or title as designated by the laboratory director) is the individual who is accountable for the technical operations of the laboratory.
- (ii) Technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. This review is conducted by a second qualified individual.
- (jj) Technician (or equivalent role, position, or title as designated by the laboratory director) is an individual who performs analytical techniques on samples under the supervision of a qualified examiner/analyst and/or performs DNA analysis on samples for inclusion in a database.
- (kk) Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.
- (ll) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for DNA analysis and includes:
 - (1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on samples.
 - (2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish and maintain a documented quality system that is appropriate to the testing activities.

3.1.1 The quality manual shall address at a minimum:

- (a) Goals and objectives
- (b) Organization and management
- (c) Personnel qualifications and training
- (d) Facilities
- (e) Sample control
- (f) Validation
- (g) Analytical procedures
- (h) Calibration and maintenance

- (i) Proficiency testing
- (j) Corrective action
- (k) Documentation
- (l) Review
- (m) Safety
- (n) Audits

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

- (a) have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.
- (b) have a technical manager or leader who is accountable for the technical operations.
- (c) have a CODIS manager or custodian who is accountable for CODIS operations.
- (d) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.

5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training and experience commensurate with the examination and testimony provided. The laboratory shall:

- 5.1.1 have a written job description for personnel to include responsibilities, duties and skills.
- 5.1.2 have a documented training program for qualifying all technical laboratory personnel.
- 5.1.3 have a documented program to ensure technical qualifications are maintained through continuing education.
 - 5.1.3.1 Continuing education - the technical manager or leader, CODIS manager or custodian, and examiner/analyst(s) must stay abreast of developments within the field of DNA typing by reading current scientific literature and by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once a year.
- 5.1.4 maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

STANDARD 5.2 The technical manager or leader shall have the following:

- 5.2.1 Degree requirements: The technical manager or leader of a laboratory

shall have, at a minimum, a Master's degree in biology-, chemistry-, or forensic science-related area and successfully completed a minimum of 12 semester or equivalent credit hours of a combination of undergraduate and graduate course work covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology), or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as statistics and/or population genetics as it applies to forensic DNA analysis.

5.2.1.1 The degree requirements of section 5.2.1 may be waived by the American Society of Crime Laboratory Directors (ASCLD) or other organizations designated by the Director of the FBI in accordance with criteria approved by the Director of the FBI. This waiver shall be available for a period of two years from the effective date of the standards. The waiver shall be permanent and portable.

5.2.2 Experience requirements: A technical manager or leader of a laboratory shall have a minimum of three years of relevant problem solving or related analytical laboratory experience.

5.2.3 Duty requirements:

5.2.3.1 General: manages the technical operations of the laboratory.

5.2.3.2 Specific duties:

- (a) Is responsible for evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by examiners.
- (b) Is responsible for technical problem solving of analytical methods and for the oversight of training, quality assurance, safety and proficiency testing in the laboratory.

5.2.3.3 The technical manager or leader shall be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.

STANDARD 5.3 CODIS manager or custodian shall have the following:

5.3.1 Degree requirements: A CODIS manager or custodian shall have, at a minimum, a Bachelor's degree in a natural science or computer science.

5.3.2 Experience requirements: A CODIS manager or custodian shall have a working knowledge of computers, computer networks, and computer database management, with an understanding of DNA profile

interpretation.

5.3.3 Duty requirements:

- (a) Is the system administrator of the laboratory's CODIS network and is responsible for the security of DNA profile data stored in CODIS.
- (b) Is responsible for oversight of CODIS computer training and quality assurance of data.
- (c) Has the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured. The state CODIS manager or custodian has this authority over all CODIS sites under his/her jurisdiction.

STANDARD 5.4 Examiner/analyst shall have the following:

- 5.4.1 Degree requirements: An examiner/analyst shall have, at a minimum, a Bachelors degree or its equivalent degree in biology-, chemistry-, or forensic science-related area and must have successfully completed college course work (graduate or undergraduate level) covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic DNA analysis, as well as course work and/or training in statistics and population genetics as it applies to forensic DNA analysis.
- 5.4.2 Experience requirements: An examiner/analyst shall have a minimum of six (6) months of DNA laboratory experience, including the successful analysis of a range of samples typically encountered in convicted offender analysis prior to independent work using DNA technology.
- 5.4.3 An examiner/analyst shall have successfully completed a qualifying test before beginning independent work responsibilities.

STANDARD 5.5 Technician shall have:

- 5.5.1 on-the-job training specific to their job function(s).
- 5.5.2 successfully completed a qualifying test before participating in DNA typing responsibilities.

STANDARD 5.6 Laboratory support personnel shall have:

- 5.6.1 training, education and experience commensurate with their responsibilities as outlined in their job description.

6. FACILITIES

STANDARD 6.1 The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure that:

- 6.1.1 Access to the laboratory is controlled and limited.
- 6.1.2 Prior to PCR amplification, evidence examinations, liquid sample examinations, DNA extractions, and PCR setup are conducted at separate times or in separate spaces.
- 6.1.3 Amplified DNA product is generated, processed and maintained in a room(s) separate from the evidence examination, liquid blood examinations, DNA extractions and PCR setup areas.
- 6.1.4 A robotic work station may be used to carry out DNA extraction and amplification in a single room, provided it can be demonstrated that contamination is minimized and equivalent to that when performed manually in separate rooms.
- 6.1.5 The laboratory follows written procedures for monitoring, cleaning and decontaminating facilities and equipment.

7. SAMPLE CONTROL

STANDARD 7.1 The laboratory shall have and follow a documented sample inventory control system. This system shall ensure that:

- 7.1.1 Offender samples are marked for identification.
- 7.1.2 Documentation of sample identity, collection, receipt, storage, and disposition is maintained.
- 7.1.3 The laboratory follows documented procedures that minimize sample loss, contamination, and/or deleterious change.
- 7.1.4 The laboratory has secure areas for sample storage including environmental control consistent with the form or nature of the sample.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methods and procedures for DNA analyses.

- 8.1.1 Developmental validation that is conducted shall be appropriately documented.

- 8.1.2 Novel database DNA methodologies shall undergo developmental validation to ensure the accuracy, precision and reproducibility of the procedure.
 - 8.1.2.1 Documentation shall be available which defines and characterizes the locus.
- 8.1.3 Internal validation shall be performed and documented by the laboratory.
 - 8.1.3.1 The procedure shall be tested using known samples. The laboratory shall monitor and document the reproducibility and precision of the procedure using human DNA control(s).
 - 8.1.3.2 Before the introduction of a procedure into database sample analysis, the analyst or examination team shall successfully complete a qualifying test.
 - 8.1.3.3 Material modifications made to analytical procedures shall be documented and subject to validation testing.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow written analytical procedures approved by the laboratory management/technical manager.

- 9.1.1 The laboratory shall have a standard operating protocol for each analytical technique used.
- 9.1.2 The procedures shall include reagents, sample preparation, extraction, equipment and controls which are standard for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

- 9.2.1 The laboratory shall have written procedures for documenting commercial supplies and for the formulation of reagents.
- 9.2.2 Reagents shall be labeled with the identity of the reagent, the date of preparation and expiration, and the identity of the individual preparing the reagent.
- 9.2.3 The laboratory shall identify critical reagents, if any, and evaluate them prior to use.

STANDARD 9.3 The laboratory shall monitor the analytical procedures using appropriate controls and standards.

9.3.1 The following controls shall be used in RFLP analysis:

9.3.1.1 When required by the analytical procedure, standards for estimating the amount of DNA recovered by extraction shall be used.

9.3.1.2 K562 as a human DNA control.

9.3.1.3 Molecular weight size markers to bracket samples on an analytical gel. No more than five lanes shall exist between marker lanes.

9.3.1.4 A procedure shall be available to monitor the completeness of restriction enzyme digestion. Interpretation of the autorad/lumigraph is the ultimate method of assessment but a test gel or other method may be used as necessary.

9.3.2 The following controls shall be used for PCR database analysis:

9.3.2.1 When required by the analytical procedure, standards which estimate the amount of human nuclear DNA recovered by extraction shall be used.

9.3.2.2 Positive and negative amplification controls.

9.3.2.3 Contamination controls.

9.3.2.3.1 Samples extracted prior to the effective date of these standards without reagent blanks are acceptable as long as other samples analyzed in the batch do not demonstrate contamination.

9.3.2.4 Allelic ladders for variable number tandem repeat sequence PCR-based systems.

STANDARD 9.4 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

STANDARD 9.5 The laboratory shall have and follow written general guidelines for the interpretation of data.

9.5.1 The laboratory shall verify that all control results are within established tolerance limits.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

- STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.
- STANDARD 10.2 The laboratory shall identify critical equipment and shall have a documented program for calibration of instruments and equipment.
- 10.2.1 Where available and appropriate, standards traceable to national or international standards shall be used for calibration.
- 10.2.1.1 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results.
- 10.2.2 The frequency of the calibration shall be documented for each instrument requiring calibration. Such documentation shall be retained in accordance with federal or state law.
- STANDARD 10.3 The laboratory shall have and follow a documented program to ensure that instruments and equipment are properly maintained.
- 10.3.1 New critical instruments and equipment, or critical instruments and equipment that have undergone repair or maintenance, shall be calibrated before use.
- 10.3.2 Written records or logs shall be maintained for maintenance service performed on instruments and equipment. Such documentation shall be retained in accordance with federal or state law.

11. REPORTS

- STANDARD 11.1 The laboratory shall have and follow written procedures for generating and maintaining documentation for database samples.
- 11.1.1 The laboratory shall have written procedures for the release of database sample information.

12. REVIEW

- STANDARD 12.1 The laboratory shall have and follow written procedures for reviewing database sample information, results, and matches.
- 12.1.1 The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewer(s).

- STANDARD 12.2 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of laboratory personnel.

13. PROFICIENCY TESTING

STANDARD 13.1 Examiners and other personnel designated by the technical manager or leader who are actively engaged in DNA analysis shall undergo, at regular intervals of not to exceed 180 days, external proficiency testing in accordance with these standards. Such external proficiency testing shall be an open proficiency testing program.

13.1.1 The laboratory shall maintain the following records for proficiency tests:

- (a) The test set identifier.
- (b) Identity of the examiner.
- (c) Date of analysis and completion.
- (d) Copies of all data and notes supporting the conclusions.
- (e) The proficiency test results.
- (f) Any discrepancies noted.
- (g) Corrective actions taken.

Such documentation shall be retained in accordance with applicable federal or state law.

13.1.2 The laboratory shall establish at a minimum the following criteria for evaluation of proficiency tests:

- (a) All reported inclusions are correct or incorrect.
- (b) All reported exclusions are correct or incorrect.
- (c) All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.
- (d) All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.
- (e) All discrepancies/errors and subsequent corrective actions must be documented.
- (f) All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.
- (g) All proficiency test participants shall be informed of the final test results.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall establish and follow procedures for corrective action whenever proficiency testing discrepancies and/or analytical errors are detected.

14.1.1 The laboratory shall maintain documentation for the corrective action. Such documentation shall be retained in accordance with federal or state law.

15. AUDITS

STANDARD 15.1 The laboratory shall conduct audits annually in accordance with the standards outlined herein.

15.1.1 Audit procedures shall address at a minimum:

- (a) Quality assurance program
- (b) Organization and management
- (c) Personnel
- (d) Facilities
- (e) Sample control
- (f) Validation
- (g) Analytical procedures
- (h) Calibration and maintenance
- (i) Proficiency testing
- (j) Corrective action
- (k) Documentation
- (l) Review
- (m) Safety
- (n) Previous audits

15.1.2 The laboratory shall retain all documentation pertaining to audits in accordance with relevant legal and agency requirements.

STANDARD 15.2 Once every two years, a second agency shall participate in the annual audit.

16. SAFETY

STANDARD 16.1 The laboratory shall have and follow a documented environmental health and safety program.

17. SUBCONTRACTOR OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST

STANDARD 17.1 A laboratory operating under the scope of these standards will require certification of compliance with these standards when a subcontractor performs convicted offender DNA analyses for the laboratory.

17.1.1 The laboratory will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor including but not limited to:

- (a) Random reanalysis of samples.
- (b) Visual inspection and evaluation of results/data.
- (c) Inclusion of QC samples.
- (d) On-site visits.